REMARKS

In response to the Office Action, claims 48, 56, 59 , 63 and 66 have been amended. Accordingly, claims 41-69 are currently pending.

Claims 48-51 and 56-69 have been rejected under 35 U.S.C 102(a) as being anticipated by U.S. Patent No. 5,967,995 to Shusterman et al. ("Shusterman").

Amended claim 48 recites a method of decomposition of waveforms in a cardiac signal comprising the steps of connecting electrodes to a patient whose heart is in Ventricular Fibrillation (VF), deriving analogue input signals from the electrodes, sampling the analogue input signals to derive the cardiac signal (EKG), and digitising the EKG signal. Wavelet transform analysis is employed to process the digitised EKG signal. Next, key features from the wavelet transform representation are extracted to predict the outcome of a specific interim therapeutic intervention during the Ventricular Fibrillation. A resuscitation protocol based on the prediction is guided by using an analytical method to determine the likely outcome of a defibrillation shock and determining whether to provide at least one interim therapeutic intervention from a group comprising defibrillatory shock, CPR and pharmaceutical, before shocking.

Amended claim 56 recites a method of decomposition of waveforms in a cardiac signal comprising the steps of connecting electrodes to a presenting patient whose heart is in Ventricular Fibrillation (VF) after the commencement of Cardio-Pulmonary Resuscitation (CPR); deriving analogue input signals from the electrodes; sampling the analogue input signals to derive the cardiac signal (EKG); digitising the EKG signal; employing wavelet transform analysis to process the digitised EKG signal; and extracting key features from the wavelet transform representation to predict the outcome of a specific interim therapeutic intervention during the Ventricular Fibrillation.

Amended claim 63 recites a method of decomposition of waveforms in a cardiac signal comprising the steps of connecting electrodes to a presenting patient whose heart is in Atrial Fibrillation (AF); deriving analogue signals from the electrodes; sampling the analogue input signals to derive the cardiac signal (EKG); digitising the EKG signal; employing wavelet transform analysis to process the digitised EKG signal; and extracting key features from the

wavelet transform representation to predict the outcome of a specific interim therapeutic intervention during the Atrial Fibrillation.

Shusterman does not disclose or suggest the steps of "connecting electrodes to a patient whose heart is in Ventricular Fibrillation (VF);" "extracting key features from the wavelet transform representation to predict the outcome of a specific interim therapeutic intervention during the Ventricular Fibrillation;" and/or "guiding a resuscitation protocol based on the prediction," as recited in amended claim 48. Nor does Shusterman disclose or suggest "extracting key features from the wavelet transform representation to predict the outcome of a specific interim therapeutic intervention during the" Ventricular or Atrial Fibrillation, as recited in amended claims 56 and 63.

In contrast, Shusterman predicts ***the onset*** of life threatening cardiac arrhythmias (LTCA). As recited in the claims, the method of the present invention predict the outcome of a specific therapy (cardioversion) ***during*** an arrhythmia, i.e. Shusterman's end point is the onset of an arrhythmia, whilst the start point of the present invention is the arrhythmia.

Importantly, Shusterman's device is not applicable *during* an LTCA because:

i) during ventricular fibrillation there are no RR intervals, QRS complexes or ST segments to be analysed – which the Shusterman invention requires; and

ii) during ventricular fibrillation prompt (immediate) therapeutic action is required as survival prognosis decreases by 50% within 4 minutes of the onset of VF hence long term monitoring (hours in the example of Shusterman et al) are completely inappropriate.

Moreover, the Karhunen-Loeve Transform used by Shusterman is not a wavelet transform in any known definition of the term. In fact, Shusterman mentions wavelet transforms only in the context of their inapplicability to the prediction of LTCA's. (col 1, lines 51-60; Col 8, lines 55-67).

The Examiner takes the position that Shusterman discloses the method connecting a patient under VF, guiding emergency protocol based on signal analysis, and determining therapeutic intervention from the analysis, and points to specific recitations in Shusterman for supporting his position. Applicants respectfully disagree and offer the following comments based upon the specific recitations of Shusterman pointed out by the Examiner:

Col 2 ; lines 44-61 pertain to the prediction of an LTCA from a comparison of sequential windows through 'tracking the changes' in consecutive windows **'1-3 hours prior to the LTCA'**. In contrast, the method of the present invention pertains to the instantaneous characterisation of an ECG *during* an arrhythmia for the prediction of defibrillation outcome.

Col 3; lines 1-23 pertain to Shusterman's invention being of utility in external defibrillators. External defibrillators (more usually AED's or ambulatory devices) are routinely used for the monitoring of patients at risk of cardiac arrest. Shusterman's invention would therefore be useful for the prediction of the onset of such an event. However, **the fact Shusterman makes reference to his invention's applicability to external defibrillators does not imply its applicability to usage during arrhythmias as suggested by the Examiner**. Shusterman's invention is not applicable for patients in cardiac arrest for the reasons outlined above. Nor does Shusterman disclose or suggest its utility during such an event at any point in the patent.

Col 3; lines 31-55 pertain to the spectral analysis of changes in the KLT of the RR intervals over time. The KLT is not a wavelet transform as in the present invention, there are no RR series during VF (there are no R waves during VF), and the present invention provides an instantaneous marker representing the health of the myocardium i.e. not derived from historic data from the current patient.

Col 4; lines 4-27 is a list of signals which Shusterman identifies as appropriate for analysis using their invention. Their invention being: 'A medical device for predicting life-threatening cardiac arrhythmias' (claim 1) (also claim 10, 15, 23). Not: a medical device for predicting the outcome of defibrillation during arrhythmia – as the present invention.

Col 5; line 20 pertains to the invention's preferred embodiment and its utility in the guidance for 'adjusting the therapy mode.' The present invention limits therapy guidance to that of therapeutic intervention **during** arrhythmia for resuscitation purposes. Shusterman provides therapeutic guidance to prevent the onset of arrhythmia '...taking appropriate preventative measures...' Col 5; line 19.

The Examiner is of the position that Shusterman 'inherently discloses' a method comprising the step of connecting electrodes to a patient 'under ventricular fibrillation' due to his assertion that Shusterman's invention is of utility in external defibrillators (citing Col 3; lines 9-10 in this regard). Applicants respectfully disagree. Under the principles of inherency, if a prior art device, *in its normal and usual operation*, would necessarily perform the method claimed, then the method claimed will be considered to be anticipated by the prior art device. See MPEP 2112. External defibrillators are routinely used for the monitoring of patients at risk of cardiac arrest. Shusterman's invention would therefore be useful for the prediction of the onset of such an event. The fact that Shusterman makes reference to his invention's applicability to external defibrillators does not therefore imply its applicability to usage **during** arrhythmias as suggested by the Examiner. Shusterman's invention is not applicable for patients in cardiac arrest for the reasons outlined above, i.e., during *its normal and usual operation*, Schusterman's device would not anticipate the claimed invention. Nor does Shusterman disclose or suggest to its utility during such events at any point in the patent.

The claims of the present invention relate to the prediction of defibrillation outcome during arrhythmia. Shusterman's invention is for the prediction of the onset of an arrhythmia. Defibrillation is a therapy only applied during an arrhythmia. De facto defibrillation is not a therapy Shusterman's invention can be used to guide. Shusterman makes no disclosure related to the prediction of defibrillation shock outcome, nor is it a therapy even mentioned within the four corners of the patent because it is not an intervention suitable for the field of the invention. Shusterman et al., do not therefore, either inherently or explicitly, disclose a method for 'guiding emergency protocol (such as resuscitation)'.

The Examiner also suggests that Shusterman's invention discloses a method comprising the step '...statistical analysis of the outcome of the defibrillation shock...'. Neither Shusterman's patent or the claims of the present invention carries out such an analysis. Claim 48 in steps (g-i) provides "an analytical method to determine the likely outcome of a defibrillation shock" for "guiding a resuscitation protocol'" i.e. "determining whether to provide at least one interim therapeutic intervention...before shocking". No analysis of the post shock ECG is claimed.

In summary, because Shusterman, during its normal and usual operation, does not recite the features of the claimed invention, Applicants respectfully submit that the claims are allowable. A prompt passage to issuance is therefore earnestly solicited.

Respectfully submitted,

Corinne R. Gorski
Registration No. 34,339

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NIXON PEABODY LLP
401 9th Street, NW
Washington, DC 20004-2128
(202) 585-8212